

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAVOL, INC.,)	
)	
Plaintiff,)	C.A. No. 12-958 (GMS)
)	
v.)	
)	
ATRIUM MEDICAL CORPORATION,)	
)	
Defendant.)	
)	

DECLARATION OF LORI WHITEHEAD

I, Lori Whitehead, hereby declare as follows:

1. I am Marketing Director for the synthetics franchise at Davol, Inc. (“Davol”). In this role, I am responsible for managing Davol’s synthetics business, which includes its range of synthetic open ventral, laparoscopic ventral and inguinal hernia repair products. I have personal knowledge of the facts stated herein and, if called to testify, would competently testify thereto.
2. Founded in Providence, Rhode Island in 1874, Davol—a subsidiary of C.R. Bard, Inc. (“Bard”)—is a leading player in the U.S. medical device industry. Davol has established this industry leadership position through an ever-expanding portfolio of proven, innovative solutions for specialized surgical procedures, including a line of prosthetics and techniques for hernia repair.
3. Two such solutions are the VENTRALEX™/VENTRALEX™ ST and VENTRIO™/VENTRIO™ ST lines of hernia patches. While both product lines are designed for use in hernia repair, they take advantage of different designs and surgical implant techniques.

4. The VENTRALEX™/VENTRALEX™ ST line of patches comprise a flexible support ring surrounded by two layers—a polypropylene mesh layer on the hernia side to provide for tissue ingrowth into the patch and promotion of hernia repair, and a barrier layer on the opposite side to minimize unwanted adhesion of the patch to internal organs. Mesh “straps” assist with placement and attachment of the patch relative to the hernia. The VENTRALEX™ patch (launched in 2002) and the VENTRALEX™ ST patch (launched in 2011) differ primarily in the materials used for the ring and barrier layer.

5. The intended use of the VENTRALEX™/VENTRALEX™ ST patches is depicted for example in the VENTRALEX™ and VENTRALEX™ ST Product Information sheets available for download from Davol’s website (true and correct copies of which are attached as Exhibits A and B, respectively):



Fig. 1: Excerpts from VENTRALEX™ Product Information (Ex. A)

6. As sold by Davol, the pouch labels for the VENTRALEX™ and VENTRALEX™ ST patches (true and correct copies of which are attached as Exhibits C and D, respectively) are marked with the numbers of several United States patents, including U.S. Patent No. 7,785,334.

7. Like the VENTRALEX™/VENTRALEX™ ST patches, the VENTRIO™/VENTRIO™ ST line of patches also include a polypropylene mesh layer on the hernia side to provide for tissue ingrowth, and a barrier layer on the opposite side to minimize unwanted

adhesion to internal organs. However, unlike the VENTRALEX™/VENTRALEX™ ST patches, the VENTRIO™/VENTRIO™ ST patches do not rely on “straps” for placement and attachment. Rather placement is achieved without straps by using a “positioning pocket” formed between the two layers. An opening in the polypropylene mesh layer allows the surgeon to insert a finger into the pocket for positioning relative to the hernia. The VENTRIO™ patch (launched in 2008) and the VENTRIO™ ST patch (launched in 2011) differ primarily in the material used for the barrier layer.

8. The intended use of the VENTRIO™/VENTRIO™ ST patches is depicted for example in the VENTRIO™ and VENTRIO™ ST Product Information sheets available for download from Davol’s website (true and correct copies of which are attached as Exhibits E and F):

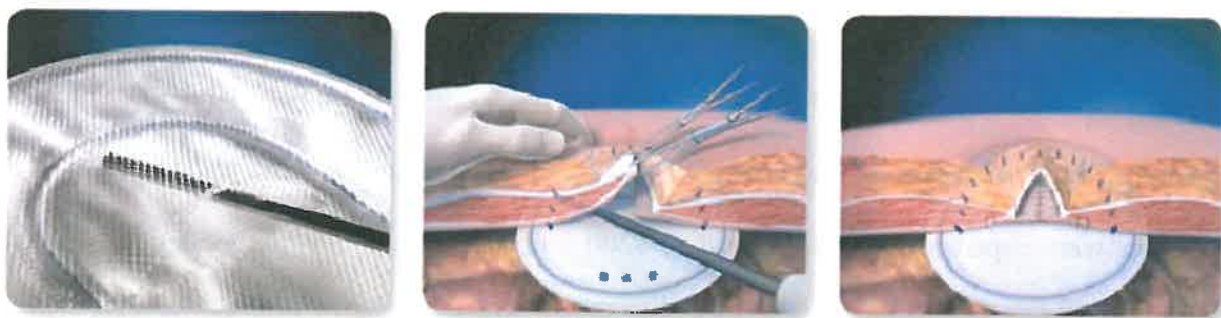


Fig. 2: Excerpts from VENTRIO™ Product Information (Ex. E)

9. As sold by Davol, the pouch labels for the VENTRIO™ and VENTRIO™ ST patches (true and correct copies of which are attached as Exhibits G and H, respectively), are also marked with the numbers of several United States patents, including U.S. Patent No. 7,824,420.

10. Since 2002, over 800,000 VENTRALEX™ and VENTRALEX™ ST patches have been implanted worldwide. The VENTRALEX™/VENTRALEX™ ST patches are the

number one choice in umbilical hernia repair, and their success is supported by numerous published clinical results. Two of the key studies are:

- D.F. Martin, R.F. Williams, T. Mulrooney, and G.R. Voeller, “Ventrelex Mesh in Umbilical/Epigastric Hernia Repairs: Clinical Outcomes and Complications,” *Hernia*, 2008—an 88 patient VENTRALEX™ study showing zero hernia recurrences; and
- H. I. A. Hadi, A. Maw, S. Sarmah, and P. Kumar, “Intraperitoneal Tension-Free Repair of Small Midline Ventral Abdominal Wall Hernias,” *Hernia*, 2006—a 51 patient study showing one recurrence.

11. Founded in 1981, Atrium Medical Corporation (“Atrium”) is one of Davol’s primary competitors in the U.S. market for synthetic hernia repair patches. In late 2011, Atrium was acquired by Maquet Cardiovascular, a subsidiary of the Getinge Group of Sweden. A Getinge Group press release issued at that time (a true and correct copy of which is attached as Exhibit I) noted that Atrium had grown an average of 19% annually in the prior five years, and its sales were expected to reach more than \$200 million in the then-current calendar year. On April 26, 2012, Atrium announced in a subsequent press release (a true and correct copy of which is attached as Exhibit J) that it would move its company headquarters “to accommodate the company’s exponential growth over the last few years.” Atrium’s President was quoted in the press release as saying that the move was required because Atrium had “grown tremendously over the last few years and is projected to continue expanding in the years to come.”

12. Within the last several years, Atrium has released a series of products designed to compete with Davol’s VENTRALEX™/VENTRALEX™ ST and VENTRIO™/VENTRIO™ ST product lines. For example, Atrium released a product called the C-QUR™ V-Patch, which

competes directly with Davol's VENTRALEX™/VENTRALEX™ ST patches in the market for dedicated umbilical hernia patches. As reflected in the Product Brochure for Atrium's C-QUR™ product line available for download from its website (a true and correct copy of which is attached as Exhibit K), the C-QUR™ V-Patch, like Davol's VENTRALEX™/VENTRALEX™ ST products, comprises a flexible support ring surrounded by a polypropylene mesh layer on the hernia side to promote tissue ingrowth, and a barrier layer to minimize unwanted adhesion with internal organs. Also like Davol's VENTRALEX™/VENTRALEX™ ST products, the C-QUR™ V-Patch uses "straps" for placement and attachment of the patch relative to the hernia:

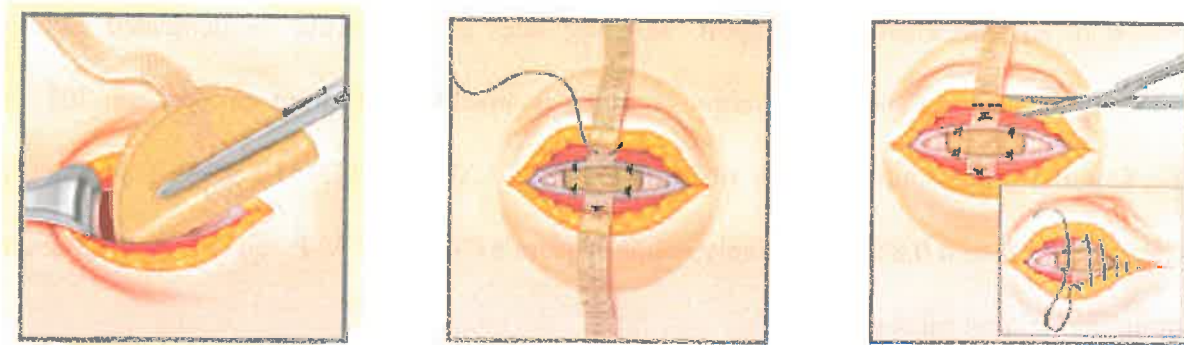


Fig. 3: Excerpts from C-QUR™ Product Brochure (C-QUR™ V-Patch) (Ex. K)

13. Atrium also sells a product called the C-QUR™ TacShield, which competes directly with Davol's VENTRIO™/VENTRIO™ ST patches in the market for dedicated open ventral hernia patches. As reflected in Atrium's C-QUR™ Product Brochure (Ex. K), the C-QUR™ TacShield, like Davol's VENTRIO™/VENTRIO™ ST products, consists of a polypropylene layer to promote natural healing and a barrier layer to minimize adhesion with internal organs, which together form a positioning pocket that can be accessed by a surgeon through an opening in the polypropylene mesh layer.

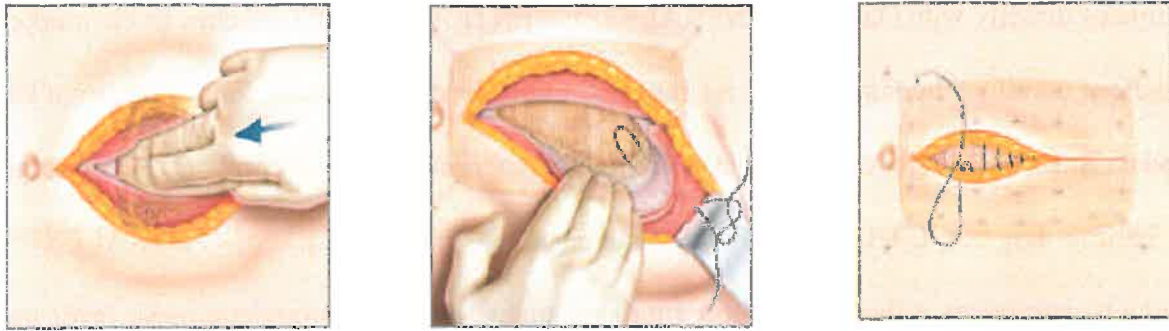


Fig. 4: Excerpts from C-QUR™ Product Brochure (C-QUR™ TacShield) (Ex. K)

14. Since its release, Atrium's C-QUR™ V-Patch has been steadily eroding the market share held by Davol's VENTRALEX™/VENTRALEX™ ST products. Indeed, as reflected in an IMS Health data report¹ showing sales in the market for dedicated umbilical hernia products (a true and correct copy of which is attached as Exhibit L), between 2011 and 2012, Davol's dollar and unit sales of the VENTRALEX™/VENTRALEX™ ST product line declined by 1.8% and 0.8% respectively, while Atrium's C-QUR™ V-Patch experienced double-digit dollar and unit sales growth.

15. Furthermore, Atrium consistently pursues the VENTRALEX™/VENTRALEX™ ST and VENTRIO™/VENTRIO™ ST businesses by selling its C-QUR™ V-Patch and C-QUR™ TacShield products at lower prices. For example, in 2012, Atrium set the average selling prices ("ASPs") for its C-QUR™ V-Patch and C-QUR™ TacShield products 16% and 39% lower than the ASPs for the corresponding VENTRALEX™/VENTRALEX™ ST and VENTRIO™/VENTRIO™ ST products, respectively (as reported by IMS, *see* Exs. L and M). Indeed, the Davol sales force reports this issue often, in particular at Outpatient Surgery Centers which tend to be more price sensitive (and are not reported by IMS). In many cases, Davol has


¹ IMS Health provides market information, including sales data, to the healthcare industry.

been forced to lower its price on the VENTRALEX™/VENTRALEX™ ST and VENTRIO™/VENTRIO™ ST patches in order to compete and keep the business. This has driven down the ASPs of these products, as evidenced by IMS ASP data (but not 100% captured because of the lack of Outpatient Surgery Center reporting).

16. If Atrium is not enjoined from selling the C-QUR™ V-Patch and C-QUR™ TacShield products, I expect the loss of market share and price erosion of Davol's corresponding VENTRALEX™/VENTRALEX™ ST and VENTRIO™/VENTRIO™ ST products to continue.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: April 4, 2013

 04/04/2013
Lori Whitehead